

## Complete Summary

---

### GUIDELINE TITLE

Standards of medical care in diabetes. I. Classification and diagnosis.

### BIBLIOGRAPHIC SOURCE(S)

American Diabetes Association (ADA). Standards of medical care in diabetes. I. Classification and diagnosis. Diabetes Care 2006 Jan;29(Suppl 1):S4-5.

### GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Standards of medical care in diabetes. I. Classification and diagnosis. Diabetes Care 2005 Jan;28(suppl 1):S4-5.

## COMPLETE SUMMARY CONTENT

SCOPE  
 METHODOLOGY - including Rating Scheme and Cost Analysis  
 RECOMMENDATIONS  
 EVIDENCE SUPPORTING THE RECOMMENDATIONS  
 BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS  
 QUALIFYING STATEMENTS  
 IMPLEMENTATION OF THE GUIDELINE  
 INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT  
 CATEGORIES  
 IDENTIFYING INFORMATION AND AVAILABILITY  
 DISCLAIMER

## SCOPE

### DISEASE/CONDITION(S)

Diabetes mellitus

- Type 1 diabetes
- Type 2 diabetes
- Other specific types of diabetes due to other causes, e.g., genetic defects in beta-cell function, genetic defects in insulin action, diseases of the exocrine pancreas (such as cystic fibrosis), and drug or chemical induced (such as in the treatment of acquired immunodeficiency syndrome [AIDS] or after organ transplantation)
- Gestational diabetes mellitus (GDM)

## GUIDELINE CATEGORY

Diagnosis

## CLINICAL SPECIALTY

Endocrinology  
Family Practice  
Geriatrics  
Internal Medicine  
Obstetrics and Gynecology  
Pediatrics

## INTENDED USERS

Advanced Practice Nurses  
Allied Health Personnel  
Dietitians  
Nurses  
Patients  
Physician Assistants  
Physicians

## GUIDELINE OBJECTIVE(S)

- To provide information on the classification of diabetes and recommendations for the diagnosis of diabetes mellitus
- To provide clinicians, patients, researchers, payers, and other interested individuals with the components of diabetes care, treatment goals, and tools to evaluate the quality of care

## TARGET POPULATION

- Children and nonpregnant adults suspected of having diabetes mellitus
- Women diagnosed with gestational diabetes mellitus during pregnancy who require postpartum evaluation

## INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Evaluation of symptoms of diabetes (e.g., polyuria, polydipsia, unexplained weight loss)
2. 75-g oral glucose tolerance test (OGTT)
3. Fasting plasma glucose (FPG) (preferred test)
4. Casual plasma glucose
5. Hemoglobin A1C (considered, but not recommended)

## MAJOR OUTCOMES CONSIDERED

Sensitivity and specificity of diagnostic tests

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

### NUMBER OF SOURCE DOCUMENTS

Not stated

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

American Diabetes Association's Evidence Grading System for Clinical Practice Recommendations

#### A

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis
- Compelling non-experimental evidence (i.e., "all or none" rule developed by the Center for Evidence Based Medicine at Oxford\*)

Supportive evidence from well-conducted randomized, controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

\*Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.

#### B

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C

Supportive evidence from poorly controlled or uncontrolled studies, including:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

E

Expert consensus or clinical experience

## METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations have been assigned ratings of A, B or C, depending on the quality of evidence (see "Rating Scheme for the Strength of the Evidence"). Expert opinion (E) is a separate category for recommendations in which there is as yet no evidence from clinical trials, in which clinical trials may be impractical, or in which there is conflicting evidence. Recommendations with an "A" rating are based on large, well-designed clinical trials or well done meta-analyses. Generally, these recommendations have the best chance of improving outcomes when applied to the population to which they are appropriate. Recommendations with lower levels of evidence may be equally important but are not as well supported.

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The recommendations were reviewed and approved in October 2005 by the Professional Practice Committee and, subsequently, by the Executive Committee of the Board of Directors.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

The evidence grading system for clinical practice recommendations (A through C, E) is defined at the end of the "Major Recommendations" field.

#### Classification and Diagnosis

- The fasting plasma glucose (FPG) is the preferred test to diagnose diabetes in children and nonpregnant adults. (E)
- The use of glycated hemoglobin test (A1C) for the diagnosis of diabetes is not recommended at this time (E)

Criteria for the Diagnosis of Diabetes	
1.	Symptoms of diabetes and a casual plasma glucose $\geq 200$ mg/dL (11.1 mmol/L). Casual is defined as any time of day without regard to time since last meal. The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss.  OR
2.	Fasting plasma glucose $\geq 126$ mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 h.  OR
3.	2-h plasma glucose $\geq 200$ mg/dL (11.1 mmol/L) during an oral glucose tolerance test (OGTT). The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75-g anhydrous glucose dissolved in water.

In the absence of unequivocal hyperglycemia, these criteria should be confirmed by repeat testing on a different day. The oral glucose tolerance test is not recommended for routine clinical use but may be required in the evaluation of patients with impaired fasting glucose or when diabetes is still suspected despite a

normal fasting plasma glucose, as with the postpartum evaluation of women with gestational diabetes mellitus.

### Definitions:

#### American Diabetes Association's Evidence Grading System for Clinical Practice Recommendations

#### A

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis
- Compelling non-experimental evidence (i.e., "all or none" rule developed by the Center for Evidence Based Medicine at Oxford\*)

Supportive evidence from well-conducted randomized, controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

\*Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.

#### B

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

#### C

Supportive evidence from poorly controlled or uncontrolled studies, including:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

E

Expert consensus or clinical experience

#### CLINICAL ALGORITHM(S)

None provided

### EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

### BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

The recommendations included are diagnostic and therapeutic actions that are known or believed to favorably affect health outcomes of patients with diabetes.

#### POTENTIAL HARMS

Not stated

### QUALIFYING STATEMENTS

#### QUALIFYING STATEMENTS

- Evidence is only one component of clinical decision-making. Clinicians care for patients, not populations; guidelines must always be interpreted with the needs of the individual patient in mind. Individual circumstances, such as comorbid and coexisting diseases, age, education, disability, and, above all, patients' values and preferences, must also be considered and may lead to different treatment targets and strategies. Also, conventional evidence hierarchies, such as the one adapted by the American Diabetes Association, may miss some nuances that are important in diabetes care. For example, while there is excellent evidence from clinical trials supporting the importance of achieving glycemic control, the optimal way to achieve this result is less clear. It is difficult to assess each component of such a complex intervention.
- While individual preferences, comorbidities, and other patient factors may require modification of goals, targets that are desirable for most patients with diabetes are provided. These standards are not intended to preclude more extensive evaluation and management of the patient by other specialists as needed.

### DESCRIPTION OF IMPLEMENTATION STRATEGY

In recent years, numerous health care organizations, ranging from large health care systems such as the U.S. Veteran's Administration to small private practices have implemented strategies to improve diabetes care. Successful programs have published results showing improvement in important outcomes such as A1C measurements and blood pressure and lipid determinations as well as process measures such as provision of eye exams. Successful interventions have been focused at the level of health care professionals, delivery systems, and patients. Features of successful programs reported in the literature include:

- Improving health care professional education regarding the standards of care through formal and informal education programs.
- Delivery of diabetes self-management education (DSME), which has been shown to increase adherence to standard of care.
- Adoption of practice guidelines, with participation of health care professionals in the process. Guidelines should be readily accessible at the point of service, such as on patient charts, in examining rooms, in "wallet or pocket cards," on Personal Digital Assistants (PDAs), or on office computer systems. Guidelines should begin with a summary of their major recommendations instructing health care professionals what to do and how to do it.
- Use of checklists that mirror guidelines have been successful at improving adherence to standards of care.
- System changes, such as provision of automated reminders to health care professionals and patients, reporting of process and outcome data to providers, and especially identification of patients at risk because of failure to achieve target values or a lack of reported values.
- Quality improvement programs combining continuous quality improvement or other cycles of analysis and intervention with provider performance data.
- Practice changes, such as clustering of dedicated diabetes visits into specific times within a primary care practice schedule and/or visits with multiple health care professionals on a single day and group visits.
- Tracking systems either with an electronic medical record or patient registry have been helpful at increasing adherence to standards of care by prospectively identifying those requiring assessments and/or treatment modifications. They likely could have greater efficacy if they suggested specific therapeutic interventions to be considered for a particular patient at a particular point in time.
- A variety of non-automated systems, such as mailing reminders to patients, chart stickers, and flow sheets, have been useful to prompt both providers and patients.
- Availability of case or (preferably) care management services, usually by a nurse. Nurses, pharmacists, and other non-physician health care professionals using detailed algorithms working under the supervision of physicians and/or nurse education calls have also been helpful. Similarly dietitians using medical nutrition therapy (MNT) guidelines have been demonstrated to improve glycemic control.
- Availability and involvement of expert consultants, such as endocrinologists and diabetes educators.



Evidence suggests that these individual initiatives work best when provided as components of a multifactorial intervention. Therefore, it is difficult to assess the contribution of each component; however, it is clear that optimal diabetes management requires an organized, systematic approach and involvement of a coordinated team of health care professionals.

## IMPLEMENTATION TOOLS

### Personal Digital Assistant (PDA) Downloads

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Living with Illness  
Staying Healthy

### IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

American Diabetes Association (ADA). Standards of medical care in diabetes. I. Classification and diagnosis. Diabetes Care 2006 Jan; 29(Suppl 1): S4-5.

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

1988 (revised 2006 Jan)

### GUIDELINE DEVELOPER(S)

American Diabetes Association - Professional Association

### SOURCE(S) OF FUNDING

The American Diabetes Association (ADA) received an unrestricted educational grant from LifeScan, Inc., a Johnson and Johnson Company, to support publication of the 2006 Diabetes Care Supplement.

## GUIDELINE COMMITTEE

Professional Practice Committee

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Vivian Fonseca, MD, Chair; Evan M. Benjamin, MD; Lawrence Blonde, MD; Kenneth Copeland, MD; Marjorie L. Cypress, MS, RN, CDE; Hertz C. Gerstein, MD, Msc, FRCPC; Irl Hirsch, MD; Steven Kahn, MB, ChB; Elizabeth Mayer-Davis, MS, PhD, RD; James Meigs, MD, MPH; Michael P. Pignone, MD, MPH; Janet H. Silverstein, MD; Geralyn R. Spollett, MSN, C-ANP, CDE; Judith Wylie-Rossett, RD, EdD; Nathaniel G. Clark, MD, MS, RD, Staff

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

## GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Standards of medical care in diabetes. I. Classification and diagnosis. Diabetes Care 2005 Jan; 28(suppl 1): S4-5.

## GUIDELINE AVAILABILITY

Electronic copies: Available from the [American Diabetes Association \(ADA\) Web site](#).

## AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Introduction. Diabetes Care 29:S1-S2, 2006
- Strategies for improving diabetes care. Diabetes Care 29:S34-S35, 2006.

Electronic copies: Available from the [American Diabetes Association \(ADA\) Web site](#).

The following are also available:

- Diagnosis and classification of diabetes mellitus. Diabetes Care 2006 Jan; 29 Suppl 1: S43-8. Electronic copies: Available from the [American Diabetes Association \(ADA\) Web site](#).
- 2006 clinical practice recommendations standards of care. Personal digital assistant (PDA) download. Available from the [American Diabetes Association \(ADA\) Web site](#).

## PATIENT RESOURCES

None available

## NGC STATUS

This summary was completed by ECRI on April 2, 2001. The information was verified by the guideline developer on August 24, 2001. This summary was updated by ECRI on March 14, 2002, July 29, 2003, May 26, 2004, July 1, 2005, and March 16, 2006.

## COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is copyrighted by the American Diabetes Association (ADA).

For information on guideline reproduction, please contact Alison Favors, Manager, Rights and Permissions by e-mail at [permissions@diabetes.org](mailto:permissions@diabetes.org).

For information about the use of the guidelines, please contact the Clinical Affairs Department at (703) 549-1500 ext. 1692.

## DISCLAIMER

### NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at <http://www.guideline.gov/about/inclusion.aspx>.

NGC, AHRQ, and its contractor ECRI make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2006 National Guideline Clearinghouse

Date Modified: 9/25/2006